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Gail Wardwell  
Signature

#53  
J.G.  
1/31/01

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re Application of:

HELDIN et al.

Serial No.: 08/453,350

Art Unit: 1646

Filing Date: May 30, 1995

Examiner: C. Saoud

Title: RECOMBINANT PDGF A-CHAIN HOMODIMERS AND  
METHODS OF USE (AS AMENDED)

RESPONSE TO NOTIFICATION OF NON-COMPLIANCE WITH 37 C.F.R. §1.192(C)

Assistant Commissioner for Patents  
Washington, D.C. 20231

Sir:

This paper is responsive to the Notification of Non-Compliance with 37 C.F.R. 1.192(c) mailed on January 2, 2001. A response is due by February 2, 2001. Accordingly, this paper is timely filed.

### **I. REMARKS**

On October 12, 2001, Appellants filed an Appeal Brief and appropriate fee. In the Notification mailed on January 2, 2001, Examiner Saoud states:

The Summary indicates that the protein preparations which are claimed are 'free of contaminating proteins of human origin that are necessarily present in protein preparations isolated from human cells' and 'free of pathogenic human viruses that frequently contaminate protein preparations isolated from human cell lines.' There is no indication as to page and line number for support of this and it would appear that this is not contained in the specification as filed. Applicant is required to provide page and line numbers for support, and this information is clearly missing from the Summary.

The recitations regarding "free of other human proteins" were presented in the Amendment filed April 7, 1997. At that time, Appellants noted that "support for the amendments ... can be found throughout the specification at, *inter alia*, page 13, lines 9-21 and in the Examples." (Amendment dated April 7, 1997, page 5). In addition, Appellants also noted that "all of the pending claims relate to PDGFA-chain homodimer preparations produced recombinantly in nonhuman cells. Thus, the preparations are free of other human proteins. [Non-recombinant] techniques would inherently result in a protein preparation that included other human protein contaminants." (Amendment dated April 7, 1997, page 11). Moreover, the Declarations on file have addressed this aspect of the claimed invention, for example, stating:

Recombinant methods of producing human PDGF A-chain, such as those described in the subject application, on the other hand, result in a preparation free of other human proteins and devoid of contaminating human viruses." (Betsholtz Declaration, paragraph 6)

Nonetheless, pursuant to the Examiner's notification, submitted herewith is a revised appeal brief containing a concise explanation of the claimed invention with references to the specification by page and line number or to drawings, as requested by Examiner Saoud. In addition, a portion of the Summary has been moved to the beginning

of the Argument section to provide a concise summary immediately before the arguments.

## II. CONCLUSION

In view of the foregoing, Appellants request that the revised Appeal Brief fully complies with the requirements of 37 CFR 1.192(c) by providing a concise explanation of the invention and properly referencing page and line numbers and drawings, where appropriate.

Please direct all further communications regarding this application to:

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Respectfully submitted,

Date: Jan 19, 2001

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